



300.1005CON

**UNITED STATES PATENT & TRADEMARK OFFICE**

Re: Serial No.: 10/796,411

Application of: Chi-Ming Chen, et al.

Filed: December 27, 2004

For: **Controlled Release Metformin Compositions**

Examiner: Young, Micah Paul

Art Unit: 1615

Docket No.: 300.1005CON

Customer No.: 23280

Mail Stop: Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

April 1, 2005

**INFORMATION DISCLOSURE**  
**STATEMENT UNDER 37 C.F.R. § 1.56**

Sir:

In accordance with the provisions of 37 C.F.R. § 1.97, Applicants hereby make of record the documents listed on the accompanying Form PTO-1449 (4 sheets) for consideration by the Examiner in connection with the examination of the above-identified patent application.

Applicants note that the following references were cited in an opposition in the corresponding Colombian Patent Application No. 03-036463 (a copy of the opposition is enclosed herewith):

- U.S. Patent No. 3,174,901, listed as reference "DN" on the accompanying Form PTO-1449;
- WO 00/28989, listed as reference "BS" on the accompanying Form PTO-1449;
- WO 99/47125, listed as reference "AM" on the accompanying Form PTO-1449; and
- U.S. Patent No. 5,955,106, listed as reference "AH" on the accompanying Form PTO-1449

Applicants further note that references "BS", "AM" and "AH" were considered by the Examiner in the parent application, U.S. Application Serial No. 09/705,630, filed November 3, 2000, now U.S. Patent No. 6,866,866, listed as reference "AA" on the accompanying Form PTO-1449.

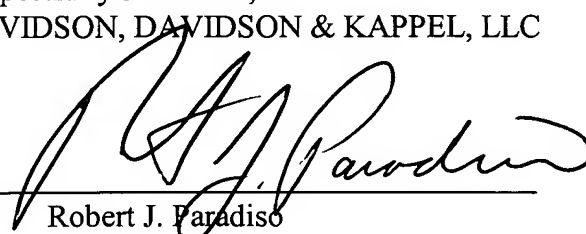
Pursuant to 37 C.F.R. § 1.98 (a), the references have been previously submitted or made of record in the parent application. If it is determined that any of the listed references are not of record in the parent application, the Examiner is requested to contact the undersigned so that a copy can be forwarded.

It is respectfully requested that the references cited in the accompanying Form PTO-1449 (4 sheets) be considered and made of record.

This Information Disclosure Statement is filed under 37 C.F.R. § 1.97 (c), before the mailing of a Final Office Action. Accordingly, a check in the amount of \$1,330.00 is enclosed, \$180.00 of which covers the fee for the filing of this Information Disclosure Statement. In the event any additional fee is due or any overpayment made in connection with the filing of this Information Disclosure Statement, the Commissioner is hereby authorized to charge said deficiency or credit overpayment to our Deposit Account No. 50-0552.

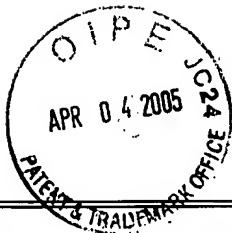
Respectfully submitted,  
DAVIDSON, DAVIDSON & KAPPEL, LLC

By



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FORM PTO-1449 (REV. 7-80) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE										ATTY. DOCKET NO. 300.1005CON		SERIAL NO. 10/796,411	
<b>LIST OF REFERENCES CITED BY APPLICANT</b> (Use several sheets if necessary)										APPLICANTS Chih-Ming CHEN, et al.			
										FILING DATE March 9, 2004		GROUP 1615	

U.S. PATENT DOCUMENTS														
EXAMINER INITIAL										DATE	NAME	CLASS	SUB- CLASS	FILING DATE IF APPROPRIATE
	AA	6	8	6	6	8	6	6		03/15/05	Chen et al.	424	468	
	AB	6	7	9	0	4	5	9		09/14/04	Cheng et al.	424	468	
	AC	6	4	7	5	5	2	1		11/05/02	Timmins et al.	424	469	
	AD	6	2	8	4	2	7	5		09/01	Chen et al.	424	473	
	AE	6	2	7	0	8	0	5		08/01	Chen et al.	424	497	
	AF	6	0	9	9	8	6	2		08/00	Chen et al.	424	473	
	AG	6	0	9	9	8	5	9		08/00	Cheng et al.	424	464	
	AH	6	0	1	0	7	1	8		1/4/00	Al-Razzak et al.	424	464	
	AI	5	9	5	5	1	0	6		09/99	Moeckel et al.	424	464	
	AJ	5	8	5	8	3	9	8		1/12/99	Cho	424	450	
	AK	5	6	9	1	3	8	6		11/25/97	Inman et al.	514	691	

FOREIGN PATENT DOCUMENTS															
										DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION	
														YES	NO
	AL	9	9	4	7	1	2	8		9/23/99	WO	A61K	9/24		
	AM	9	9	4	7	1	2	5		9/23/99	WO	A61K	9/20		
	AN	9	9	2	9	3	1	4		6/17/99	WO	A61K	31/155		
	AO	9	6	0	8	2	4	3		3/21/96	WO	A61K	31/155		

OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)	
AP	<i>Physicians' Desk Reference</i> (54 <sup>th</sup> Ed. 2000), pp. 831-835.
AQ	Sheen, Andre J., <i>Clinical Pharmacokinetics of Metformin</i> , <i>Clinical Pharmacokinetics</i> , May 30, 1996, 5:359-371.
AR	Bailey, Clifford J., et al., <i>Metformin</i> , <i>The New England Journal of Medicine</i> , Feb. 29, 1996, 334:574-579.
AS	Dunn, Christopher J., et al., <i>Metformin: A Review of its Pharmacological Properties and Therapeutic Use in Non-Insulin-Dependent Diabetes Mellitus</i> , <i>Drugs</i> (1995), 49:721-747.
AT	Karttunen, P., et al., <i>The Pharmacokinetics of Metformin: A Comparison of the Properties of a Rapid-Release and a Sustained-Release Preparation</i> , pp. 31-36.

EXAMINER	DATE CONSIDERED
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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EXAMINER INITIAL									DATE	NAME	CLASS	SUB- CLASS	FILING DATE IF APPROPRIATE		
	BA	5	6	8	8	5	1	8	11/18/97	Ayer et al.	424	422			
	BB	5	6	7	4	9	0	0	10/7/97	Ubillas et al.	514	557			
	BC	5	6	6	8	1	1	7	9/16/97	Shapiro	514	55			
	BD	5	6	6	7	8	0	4	9/16/97	Wong et al.	424	472			
	BE	5	6	5	0	1	7	0	7/22/97	Wright et al.	424	473			
	BF	5	6	3	1	2	2	4	5/20/97	Efendic et al.	514	12			
	BG	5	6	2	9	3	1	9	5/13/97	Luo et al.	514	284			
	BH	5	6	1	4	5	7	8	3/25/97	Dong et al.	524	377			
	BI	5	5	9	1	4	5	4	1/7/97	Kuczynski et al.	424	486			
	BJ	5	5	4	5	4	1	3	8/13/96	Kuczynski et al.	424	473			
	BK	5	5	4	3	1	5	6	8/6/96	Roorda et al.	424	484			
	BL	5	5	1	2	2	9	3	4/30/96	Landrau et al.	424	449			
	BM	5	4	1	3	5	7	2	5/9/95	Wong et al.	604	892.1			
	BN	5	3	0	8	3	4	8	5/3/94	Balaban et al.	604	892.1			
	BO	5	1	8	5	1	5	8	2/9/93	Ayer et al.	424	473			
	BP	5	1	7	8	8	6	7	1/12/93	Guittard et al.	424	473			
	BQ	5	1	4	1	7	5	2	8/25/92	Ayer et al.	424	473			
	BR	5	1	2	0	5	4	8	6/9/92	McClelland et al.	424	473			
FOREIGN PATENT DOCUMENTS															
									DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION		
													YES	NO	
	BS	0	0	2	8	9	8	9	05/00	WO	A61K	353			
OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)															
	BT	Andrx Pilot Biostudy Data (20 pages)													
EXAMINER										DATE CONSIDERED					
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EXAMINER INITIAL	CA	5	1	1	4	5	9	7	DATE	NAME	CLASS	SUB- CLASS	FILING DATE IF APPROPRIATE
	CA	5	1	1	4	5	9	7	5/5/92	Wong et al.	424	438	
	CB	5	0	9	1	1	9	0	2/25/92	Kuczynski et al.	424	473	
	CC	5	0	7	1	6	0	7	12/10/91	Ayer et al.	264	112	
	CD	5	0	5	5	3	0	6	10/08/91	Barry et al.	424	482	
	CE	5	0	2	4	8	4	3	6/18/91	Kuczynski et al.	514	255.06	
	CF	4	9	6	3	1	4	1	10/16/90	Eckenhoff	604	892.1	
	CG	4	8	9	2	7	3	9	1/9/90	Shah et al.	424	473	
	CH	4	8	6	5	5	9	8	9/12/89	Eckenhoff	604	892.1	
	CI	4	8	5	1	2	2	9	7/25/89	Magruder et al.	424	457	
	CJ	4	7	8	3	3	3	7	11/8/88	Wong et al.	424	468	
	CK	4	7	7	7	0	4	9	10/11/88	Magruder et al.	424	457	
	CL	4	7	0	4	1	1	8	11/3/87	Eckenhoff	424	438	
	CM	4	6	9	2	3	3	6	9/8/87	Eckenhoff et al.	424	468	
	CN	4	6	2	7	8	5	0	12/9/86	Deters et al.	604	892.1	
	CO	4	6	2	4	8	4	7	11/25/86	Ayer et al.	424	467	
	CP	4	6	1	5	6	9	8	10/7/86	Guittard et al.	604	892.1	
	CQ	4	6	1	2	0	0	8	9/16/86	Wong et al.	604	892.1	

FOREIGN PATENT DOCUMENTS														
									DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION	
													YES	NO
	CR													

OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)	
CS	Chio, C. Sustained-Release Drug Delivery Systems Remington: the Science and Practice of Pharmacy, 1995, Mack Publishing Company, Easton PA pp 1660-1669

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	DA	4	6	0	9	3	7	4	9/2/86	Ayer	424	473	
	DB	4	5	8	7	1	1	7	5/6/86	Edgren et al.	424	473	
	DC	4	5	2	2	6	2	5	6/11/85	Edgren	424	473	
	DD	4	1	1	1	2	0	1	9/5/78	Theeuwes	424	473	
	DC	4	0	8	8	0	0	4	5/9/78	Theeuwes et al.	219	121.71	
	DF	4	0	8	0	4	7	2	3/21/78	Bohuon	514	555	
	DG	4	0	7	7	4	0	7	3/7/78	Theeuwes et al.	424	427	
	DH	4	0	6	3	0	6	4	12/13/77	Saunders et al.	219	121.7	
	DI	4	0	3	6	2	2	8	7/19/77	Theeuwes	424	473	
	DJ	4	0	3	4	7	5	8	7/12/77	Theeuwes	424	427	
	DK	4	0	0	8	7	1	9	2/22/77	Theeuwes et al.	424	427	
	DL	3	9	5	7	8	5	3	5/18/76	Bohuon	560	143	
	DM	3	9	5	2	7	4	1	4/27/76	Baker	424	405	
	DN	3	9	1	6	8	9	9	11/4/75	Theeuwes et al.	424	424	
	DO	3	8	4	5	7	7	0	11/5/74	Theeuwes et al.	424	427	
	DP	3	6	2	1	0	9	7	11/16/71	Scott	424	247	
	DQ	3	1	7	4	9	0	1	03/23/65	Sterne	514	635	

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	DR														

OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)														
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